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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,243	09/09/1999	JOHN H. LEE	27338	9819

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/392,243

**Applicant(s)**

LEE ET AL.

**Examiner**

Francisco C. Prats

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 36-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-27, 53 and 54 is/are allowed.
- 6) ☒ Claim(s) 36-39, 45, 51 and 52 is/are rejected.
- 7) ☒ Claim(s) 40-44 and 46-50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

This action is in response to the decision by the Board of Patent Appeals and Interferences (BPAI) on February 4, 2005.

Prosecution is hereby reopened. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 21-27 and 36-54 are pending and are examined on the merits.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-39 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hiles et al (U.S. Pat. 6,666,892) in light of <http://www.vh.org/adult/provider/anatomy/MicroscopicAnatomy/Section10/Plate10192.html> (hereinafter "Virtual Hospital").

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As pointed out in the Board decision of February 4, 2005, Hiles discloses the use of hydrogen peroxide in the treatment of mucosa tissue. Specifically, Hiles discloses the preparation of collagen-containing "tela submucosa," or small intestine submucosa, from sources thereof. See, e.g., column 3, lines 14-40. The submucosa may be prepared by rinsing a source, such as intestine, with a solvent, followed by treating with a disinfecting agent. See, column 4, lines 44-65. A preferred disinfecting agent is hydrogen peroxide, which may be used at concentrations of 0.05% to 30% by volume, for a preferred duration of 180 to 210 minutes. See, column 4, line 66 through column 5, line 15.

Intestine inherently contains mucosa. See Virtual Hospital. Thus, by disclosing the treatment of a submucosa source, such as intestine, with hydrogen peroxide, Hiles inherently describes the treatment of mucosa with hydrogen peroxide, as recited in the rejected claims.

Lastly, note specifically that this rejection is not applicable to claims reciting preservation of mucosa. While the Board urges that column 7, lines 1-8, of Hiles demonstrates that mucosa tissue will not be damaged by the disinfectant treatment, it is in fact the submucosa which retains the desirable physical and mechanical properties. Submucosa is a different tissue than

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mucosa. See Virtual Hospital. Thus, rather than preserving the mucosa, it is Hiles' vigorous treatment of with disinfectants that removes undesirable mucosa-carried contaminants from sources such as intestine, thereby producing a collagenous submucosa preparation which is clearly distinct from mucosa, as evidenced by Virtual Hospital.

***Claim Rejections - 35 USC § 102/103***

Claims 36-39, 45, 51 and 52 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hiles et al (U.S. Pat. 6,666,892) in light of <http://www.vh.org/adult/provider/anatomy/MicroscopicAnatomy/Section10/Plate10192.html> ("Virtual Hospital").

As discussed above, the reference discloses a process which appears to be identical to the presently claimed process, based on the fact that the prior art process contacts a product containing the claimed mucosa tissue with the claimed disinfectant, hydrogen peroxide. Consequently, the claimed process appears to be anticipated by the reference.

However, because there is no specific exemplification of contacting mucosa with hydrogen peroxide, one might not consider Hiles to describe a single embodiment which anticipates the

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rejected claims. Despite this, in view of the direct teachings of the suitability of using mucosa-containing intestine as a starting material, and hydrogen peroxide as a disinfectant, Hiles provides ample motivation for practicing the invention as recited in the rejected claims.

Further still, as to claims 51 and 52, it is not clear that the mucosa-containing intestine would necessarily contain the claimed amount of ash. However, even if the reference process and the claimed process are not one and the same in this respect, and there is, in fact, no anticipation, the reference process would, nevertheless, have rendered the claimed process obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected differing tissues from different sources and organs to vary with respect to ash content. Thus, the selection of a specific starting material, having a specific ash content as recited in claim 51, for Hiles' process, clearly would have been matter of selecting from among known equivalent starting materials specifically enumerated by Hiles, for example at column 3, line 63, through column 4, line 18. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

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Claims 21-27, 53 and 54 are allowed. Claims 40-44 and 46-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
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